

FEB - 9 2001

Exactech® AcuMatch™ Integrated Hip System
M-Series Femoral Stem Component
High & Low Off-Set Neck Segments

510(k) Summary of Safety and Effectiveness

Sponsor: Exactech® Inc.
2320 N.W. 66th Court
Gainesville, Florida 32653

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FDA Establishment Number 1038671

Contact: Gary J. Miller, Ph.D.
Executive V.P. of Research and Development

Date: January 10, 2001

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510(k) Summary of Safety and Effectiveness

Trade Name: Exactech® AcuMatch M-Series
High Off-Set Neck
Low Off-Set Neck

Common Name: Total Hip Prosthesis Femoral Component

Classification Name: Prosthesis, Hip, Semi-Constrained, Metal/Polymer,
Porous, Uncemented (Femoral Component)

Product Code: LPH

Device Class: II

Classification Panel: Orthopedic

Legally Marketed Devices for Substantial Equivalence Comparison:

<u>Model</u>	<u>Manufacturer</u>	<u>510(k)</u>
M-Series	Exactech Inc.	#K993736

S-Rom	Joint Medical Products	
Impact	Biomet	
Mallory Head	Biomet	
Link	Link America	

The AcuMatch M-Series high and low off-set neck segments are made of similar materials and are of a similar design to other legally marketed modular femoral components. Most notably, the proposed neck segments are equivalent in materials and design to the Exactech's predicate M-Series neck segments. M-Series components are also similar to the "S-ROM" by Joint Medical Products Corporation, the Biomet "Impact", and "Mallory-Head" and the "Link MP" by Link America.

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Description:

The Exactech Modular Stem is a four-piece system consisting of a proximal neck segment, metaphyseal segment, diaphyseal segment and a locking screw. All of the components are interchangeable, therefore allowing for many sizing combinations to meet varying anatomical situations. The components are composed of titanium alloy. Design changes were made to the original neck segments cleared through premarket notification #K993736:

- A. High Offset Neck Segments
 - 1. Material was added to the lateral radius of all neck segments.
 - 2. A new “-5 Neck Segment” model was added.
- B. Low Offset Neck Segments

A new “Low Offset” Neck version of neck is proposed. These models represent a reduction in horizontal offset of 5mm as compared to the predicate design (#K993736):

 - 1. Low Offset -5 Neck Segment
 - 2. Low Offset Standard (+0) Neck Segment
 - 3. Low Offset +10 Neck Segment

Intended Use:

AcuMatch M-Series components are indicated for use in skeletally mature individuals undergoing primary surgery for total hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, ankylosing spondylitis, congenital hip dysplasia, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of the M-Series are also potentially indicated for revision of failed previous reconstructions where sufficient bone stock is present and to restore mobility resulting from previous fusion.

The AcuMatch M-Series components are indicated for press-fit and cemented applications.

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Contraindications:

AcuMatch M-Series components are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, in neuromuscular disorders that do not allow control of the hip joint, and in patients whose weight, age, or activity level would cause the surgeon to expect early failure of the system.

Performance Data Summary:

Finite Element Analysis was conducted to verify that the performance of the proposed high and low off-set neck segments would be adequate for anticipated *in-vivo* loading. The results showed that the proposed devices have performance characteristics equivalent to or greater than Exactech's predicate M-Series neck design.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB - 9 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lisa Simpson
Regulatory Representative
Exactech
2320 NW 66th Court
Gainesville, Florida 32653

Re: K010120

Trade Name: Exactech® Integrated Hip System
AcuMatch™ M-series Femoral Stem Component High and Low Offset
Neck Segments

Regulatory Class: II

Product Code: LPH

Dated: January 10, 2001

Received: January 16, 2001

Dear Ms. Simpson:

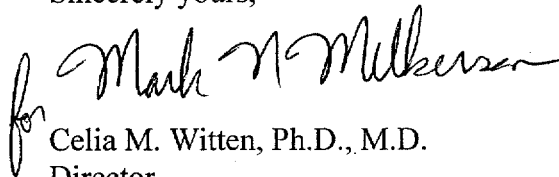
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for Mark N. Milbranson

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**Exactech® AcuMatch™ Integrated Hip System
M-Series Femoral Stem Component**

Indications for Use

510(k) Number: K 010120

Device Name: **Exactech Integrated Hip System**
AcuMatch M-Series Femoral Stem Component
High Off-Set Neck Segment
Low Off-Set Neck Segment

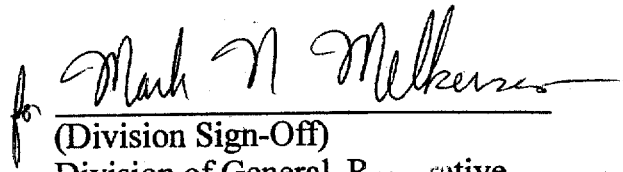
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(Division Sign-Off)
Division of General, Reproductive
and Neurological Devices

510(k) Number K 010120

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use 7-12

or

Over the Counter Use N2